Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Clinical study of patient-specific bone implant prepared via 3D printing method for craniofacial surgery applications

Protocol summary

Study aim
Clinical evaluation of hydroxyapatite and polycaprolactone implants prepared via 3D printing method for craniofacial surgery applications

Design
It is a non randomized single group clinical trial with 7 patients receiving 3D printed craniofacial implants enrolling between April 2022 and February 2023, and will be followed for six months.

Settings and conduct
The prepared implants will be used in 7 patients. After implant placement and fixation, the skin will be sutured. In 7 to 10 days after surgery, a clinical evaluation of the patient will be performed. In 3 and 6 months after surgery, CT scan images will be provided to examine the bone regeneration and implant degradation ratio.

Participants/Inclusion and exclusion criteria
Patients over 6 years old who suffer from craniofacial defects and the use of plates in surgery cannot correct the shape of the bone. Exclusion criteria: Having an underlying disease, including allergies.

Intervention groups
The intervention group is investigating the effectiveness and durability of 3D printed implants made of polycaprolactone and hydroxyapatite (40% wt). These implants are intended for trauma patients or patients with natural birth defects with bone deformities in the skull and face area. Implants will be administered during surgery after general anesthesia. The implants are prepared in collaboration with Adli Tissue Regeneration company.

Main outcome variables
Newly formed bone density; the rate of new bone formation; biodegradation rate of the implant; patient sensitivity to ambient temperature changes;

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220807055633N1**
Registration date: **2022-09-16, 1401/06/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-16, 1401/06/25**
Update count: **0**

Registration date
2022-09-16, 1401/06/25

Registrant information

Name
Seyed Ali Poursamar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 3865

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ali.poursamar@amt.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-31, 1401/05/09

Expected recruitment end date
2023-01-29, 1401/11/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical study of patient-specific bone implant prepared via 3D printing method for craniofacial surgery applications

Public title
Evaluation of 3D printed bone implant in skull and the face surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People who have skull and face defects and the use of plates in surgery cannot correct the shape of the bone.
Exclusion criteria:
Having an underlying disease, including allergies
Age
From **20 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **7**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Hezar Jerib Avenue
City
esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-07-31, 1401/05/09
Ethics committee reference number
IR.ARI.MUI.REC.1401.132

Health conditions studied

1

Description of health condition studied
Absorbable bone implants to correct craniofacial abnormalities
ICD-10 code
Z96.7
ICD-10 code description
Presence of other bone and tendon implants

Primary outcomes

1

Description
New bone formation
Timepoint
3 and 6 months after implant placement
Method of measurement
Providing CT scan images

Secondary outcomes

1

Description
biodegradation rate of the implant
Timepoint
3 and 6 months after implant placement
Method of measurement
Providing CT scan images

Intervention groups

1

Description
Intervention group: Personalized 3D printed biodegradable implants comprised of polycaprolactone and hydroxyapatite (40% Wt) made by Adli Tissue Regeneration company are utilized during surgery for patients who suffer from bone abnormalities in the skull and face.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan University of Medical Sciences
Full name of responsible person
Seyed Ali Poursamar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Seyed Ali Poursamar
Position
Assistant Professor
Latest degree
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Tissue Engineering
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available